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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,887	03/30/2004	Edward Ashton	116741-00238	1329
27557	7590	01/11/2006	EXAMINER	
BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037			HORWAT, JENNIFER A	
			ART UNIT	PAPER NUMBER

3737

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/811,887	Applicant(s) ASHTON, EDWARD	
	Examiner Jennifer Horwat	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In response to applicant's communication dated 12/19/2005 regarding the last Office action, the following corrective action is taken.

The period for reply of 3 MONTHS set in said Office Action is restarted to begin with the mailing date of this letter.

2. A corrected copy of the last Office Action is enclosed.

Information Disclosure Statement

3. The information disclosure statement filed on 6/10/2005 is in compliance with 37 CFR 1.97-1.98 and all references therein have been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 recites the limitation "wherein the gradient-descent energy minimization" in the claim. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 16 was intended to be dependent on claim 15 instead of claim 11 which would resolve the problem of insufficient antecedent basis, and was interpreted as such for purposes of examination.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 5-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Lin, et al (US 6745066). Lin discloses a method for imaging and identifying a region of interest in medical images which includes receiving image data into a computing device (figure 1), receiving an identification of plasma region of interest (claim 1) in which a value is calculated for each voxel (col 6, line 19) using slope (col 6, line 16), peak value (col 5, line 55), and conformance to a gamma variate curve (col 6, line 13) at time of maximum uptake (col 5, lines 26-30) in order to determine inclusion in region of interest. The intensity values are determined at the time at which the contrast agent is at maximum concentration and is calculated using a time0density curve (col 5, lines 15-20). Optionally, the region may be input manually by a user (figure 3, step 132). The device for identifying the region of interest includes an input for receiving image data (figure 1, element 50), a region-identifying device (figure 1, element 78), and a computing device (figure 1, element 110), which carry out the steps of the method previously discussed. A pointing device is inherent in the fact that the "diagnostician draws a circle around an artery in the reference slice" (col 7, lines 19-21) in the user

input step, as either a computer mouse, the diagnostician's finger, or other known pointing device would be inherently required to allow the diagnostician to delineate the region of interest.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 4, 9-13, 17-23, and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin in view of Rijpkema, et al ("Method for Quantitative Mapping of Dynamic MRI Contrast Agent Uptake in Human Tumors"). Lin, as discussed above, discloses a method and device for automatically identifying a region of interest for blood flow imaging using optimization methods and for those elements not previously discussed also teaches correcting for inter-frame motion (figure 3, step 130). However, Lin fails to disclose using the method to estimate a volume transfer constant between blood plasma and extra-vascular extra-cellular space. Rijpkema discloses a method for quantitative mapping of dynamic MRI contrast agent uptake in human tumors which includes receiving image data, identifying tumor margins (page 459, results), determining uptake curves (page 459, results), and estimating the volume transfer constant, k_{trans} , from the data (page 458). Additionally, Rijpkema discloses forming an image representing the volume transfer constant, as seen in figure 2b. The

identification of plasma region is determined from the time to maximum contrast concentration (page 458, column 2) in order to set a threshold for inclusion in the region. Claims 9-13 teach the method steps, as set forth above, and the structures in claims 19-23 required for computing the necessary calculations are considered inherently taught by the disclosure. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device as disclosed by Lin with the teachings of Rijpkema, as Rijpkema discloses a specific use, namely volume transfer constant estimation, of the more general method for blood perfusion study disclosed by Lin, which would benefit from the automation and motion correction additionally disclosed by Lin to provide a more accurate and faster image representation.

10. Claims 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin and Rijpkema as applied to claims 11 and 21 above, respectively, and further in view of Gilhuijs, et al (US 6112112). Rijpkema, as discussed above, discloses identifying tumor margins in the image data, however fails to disclose that the margins are determined through geometrically constrained region growth. However, Gilhuijs teaches an automated method for "assessment of tumor extent in MR images" (col 4, lines 23-24) that uses volume growing to generate the extent of the tumor. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method and device as disclosed by Lin and Rijpkema with the teachings of Gilhuijs to provide a more "accurate quantification of the shape and extent" (col 1, lines 16-17) of the tumor.

11. Claims 15, 16, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin and Rijpkema as applied to claims 10 and 20 above, and further in view of Kirk, et al (US 5329478). Lin and Rijpkema, as discussed above, substantially disclose the invention as claimed. Rijpkema discusses solving for the volume transfer constants, as shown on page 458, using the "Larson model" implemented in a Matlab routine which computes in 2 hours, but fails to disclose solving for the constants through gradient-descent energy minimization. However, Kirk teaches that "one common approach to optimization is gradient descent" and that an "annealing style" of optimization, wherein the gradient optimization process repeats from each subsequent step, which will prevent the process from stopping at local minima while descending to the global minimum of the function. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a gradient-descent energy minimization to solve the volume transfer constant equation, as it is advantageous to avoid local minima and use a method that ensures a global minimum.

Conclusion


12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mistretta and Brady teach methods of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jah
01/03/2006


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